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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,906	02/27/2004	Steven D. Girouard	279.696US1	4545

21186 7590 09/23/2005

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/788,906	GIROUARD ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-148* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-148* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-78, drawn to a device, classified in class 607, subclass 3.

II. Claims 79-123, drawn to a method to control gene expression, classified in class 435, subclass 450.

III. Claims 124 and 127-129, drawn to a process of preparing an implantable device effective to control gene expression, classified in class 435, subclass 440.

IV. Claims 125-148, drawn to a method to control expression of at least one exogenously introduced expression cassette, classified in class 435, subclass 450.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process that does not detect the predetermined cardiac condition from the physiological signal but simply senses the physiological signal.

3. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make a materially different product such an implantable deice that does not

does not comprise a sensor to sense a physiological signal indicative of a cardiac condition, but rather one that senses a neurological signal or respiratory signal.

4. Inventions IV and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process that does not control expression of at least one exogenously introduced expression cassette but rather one that simply senses a physiological signal and delivers a regulatory signal in response to a detection of a cardiac condition.

5. Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not include the steps of preparing an implantable device effective to control expression of at least one exogenously introduced expression cassette. The subcombination has separate utility such as use by itself or use not requiring sensing a cardiac condition but by continuously administering therapy.

6. Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination

does not include the steps of providing an animal or introducing the animal to at least one expression cassette. The subcombination has separate utility such as use by itself or use not requiring detecting the condition from a sensor but by a doctor's input.

7. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, as seen by their different preambles, the different inventions have different functions and effects. Invention III is a method to prepare an implantable medical device for gene therapy and results in a device capable of such functions. Invention IV is a method to control expression of at least one exogenously introduced expression cassette and results in an animal receiving cardiac therapy via device controlled gene expression.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

IN ADDITION TO THE RESTRICION ABOVE SPECIES MUST BE CHOSEN BELOW:

9. If Group I is chosen above, this application contains claims directed to the following patentably distinct species of the claimed invention:

Species I, the embodiment wherein the gene regulatory signal delivery device comprises an electric field generator which emits an electric field.

Species II, the embodiment wherein the gene regulatory signal delivery device comprises a light emitter which emits a light having a predetermined wavelength.

Species III, the embodiment wherein the gene regulatory signal delivery device comprises a speaker which emits an acoustic energy.

Species IV, the embodiment wherein the gene regulatory signal delivery deice comprises a drug delivery device which contains a chemical agent.

Species V, the embodiment wherein the gene regulatory signal delivery deice comprises a thermal radiator which emits a thermal energy.

Species VI, the embodiment wherein the gene regulatory signal delivery device comprises an electric field generator which emits an electromagnetic field

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable or generic.

10. If Group I is chosen above, this application contains claims directed to the following patentably distinct species of the claimed invention:

Species A, the embodiment wherein the event detector comprise an arrhythmia detector.

Species B, the embodiment wherein the event detector comprise an atrial fibrillation detector.

Species C, the embodiment wherein the event detector comprise a ventricular defibrillation detector.

Species D, the embodiment wherein the event detector comprise an ischemia detector.

Species E, the embodiment wherein the event detector comprise a systolic dysfunction detector.

Species F, the embodiment wherein the event detector comprise a diastolic dysfunction detector.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable or generic.

11. If Group I is chosen above, this application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1, the embodiment wherein the sensor comprises an electrogram sensing circuit.

Species 2, the embodiment wherein the sensor comprises a metabolic sensor.

Species 3, the embodiment wherein the sensor comprises an impedance sensor to sense tissue impedance.

Species 4, the embodiment wherein the sensor comprises a pressure sensor to sense a pressure in a cardiovascular system.

Species 5, the embodiment wherein the sensor comprises a stroke volume sensor.

Species 6, the embodiment wherein the sensor comprises a neural activity sensor.

Species 7, the embodiment wherein the sensor comprises a heart rate variability detector.

Species 8, the embodiment wherein the sensor comprises a renal function sensor.

Species 9, the embodiment wherein the sensor comprises an acoustic sensor adapted to sense at least one of heart sounds and respiratory sounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable or generic.

12. If Group II is chosen above, this application contains claims directed to the following patentably distinct species of the claimed invention:

Species I, the embodiment wherein the method includes the step wherein an electric field is delivered.

Species II, the embodiment wherein the method includes the step wherein a light having a predetermined wavelength is delivered.

Species III, the embodiment wherein the method includes the step wherein an acoustic energy is delivered.

Species IV, the embodiment wherein the method includes the step wherein a chemical agent is delivered.

Species V, the embodiment wherein the method includes the step wherein a thermal energy is delivered.

Species VI, the embodiment wherein the method includes the step wherein an electromagnetic field is delivered.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable or generic.

13. If Group II is chosen above, this application contains claims directed to the following patentably distinct species of the claimed invention:

Species A, the embodiment wherein detecting the predetermined cardiac condition comprises detecting an arrhythmia.

Species B, the embodiment wherein detecting the predetermined cardiac condition comprises detecting an atrial fibrillation.

Species C, the embodiment wherein detecting the predetermined cardiac condition comprises detecting a ventricular fibrillation.

Species D, the embodiment wherein detecting the predetermined cardiac condition comprises detecting ischemia.

Species E, the embodiment wherein detecting the predetermined cardiac condition comprises detecting a systolic dysfunction.

Species F, the embodiment wherein detecting the predetermined cardiac condition comprises detecting a diastolic dysfunction.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable or generic.

14. If Group II is chosen above, this application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1, the embodiment wherein sensing the physiological signal comprises sensing at least one electrogram.

Species 2, the embodiment wherein sensing the physiological signal comprises sensing a signal indicative of cardiac metabolic level.

Species 3, the embodiment wherein sensing the physiological signal comprises sensing a tissue impedance.

Species 4, the embodiment wherein sensing the physiological signal comprises sensing a pressure in a cardiovascular system.

Species 5, the embodiment wherein sensing the physiological signal comprises sensing a stroke volume.

Species 6, the embodiment wherein sensing the physiological signal comprises sensing a neural activity.

Species 7, the embodiment wherein sensing the physiological signal comprises sensing a heart rate variability.

Species 8, the embodiment wherein sensing the physiological signal comprises sensing a renal function.

Species 9, the embodiment wherein sensing the physiological signal comprises sensing at least one of heart sounds and respiratory sounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable or generic.

15. If Group IV is chosen above, this application contains claims directed to the following patentably distinct species of the claimed invention:

Species I, the embodiment wherein the at least one expression cassette is present in a viral vector.

Species II, the embodiment wherein the at least one expression cassette is present in a DNA vector.

Species III, the embodiment wherein the at least one expression cassette is present in a plasmid vector.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable or generic.

16. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an

allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jessica L. Reidel